The effectiveness of a domiciliary facial cooling therapy system on generic Quality of Life, following mandibular third molar removal

INTRODUCTION

Third molar extraction is the most commonly performed procedure by Oral and Maxillofacial Surgeons in the UK (1). The surgical procedure to extract a M3M can be complicated by moderate to severe pain and swelling, and represent a significant amount of morbidity within the immediate post-operative period for some patients (2).

Quality of life (QoL) is defined as a patient's perception of the impact of their disease and/ or treatment on their daily life, and their physical, psychological and social functioning or well-being (3). Previous studies focusing on QoL following M3M removal have shown a deterioration in "oral health-related quality of life", to include pain and swelling, directly following their procedure (2,4,5,6,7).

In this evaluation we used the EQ5D3L questionnaire (Figures 1 & 2). This instrument was originally derived to evaluate patient-reported impact of conditions and to compare the economic effectiveness of different interventions after conversion to a country-specific tariff. In a previous validation study, we found that patients rank individual domains of the EQ5D3L as highly relevant measures of their QoL following M3M removal (8). We therefore chose to use individual domains of the EQ5D3L to evaluate the potential impact of hilotherapy on QoL following M3M. .

The use of cooling compresses have traditionally been used for the reduction of postoperative pain and swelling, however their effectiveness has been questioned in studies that objectively measure these parameters (9). The Hilotherm® non-domiciliary facial cooling system delivers a consistent low therapeutic temperature (15°C), and meta-analyses have demonstrated a reduction in pain and swelling following orthognathic surgery, with excellent patient compliance and improved patient satisfaction when compared to traditional cooling packs/ compresses (10).

As part of a service evaluation we collected patient feedback on a novel Hilotherm® domiciliary facial cooling system in the early post-operative period following M3M removal. We aimed to evaluate ease of use, and effectiveness at improving QoL following M3M removal.

METHODS

We recorded patients' Quality of Life (QoL) using the EQ5D3L Parts 1 & 2 (Figures 1 & 2), daily for 7 days, following M3M removal (permission granted for use by EuroQol Group Foundation on this patient number on 16/01/2014). Inclusion criteria were; Class I or II by the American Society of Anesthesiologists (ASA), aged 18 to 25 and non-smoker. They required removal of at least one horizontal, or mesio-angular impacted M3M with a surgical approach defined by the raising of a muco-periosteal flap, bone removal and tooth sectioning. Exclusion criteria were; immunosuppressant diseases or drugs, chronic pain syndromes, and known illicit drug use. All patients were treated under a general anaesthetic by the same surgeon in the day surgery unit of a district general hospital.

20 consecutive patients undergoing M3M removal without using the domiciliary facial cooling system (Group 1) completed the EQ5D3L QoL survey. The questionnaire was printed on to seven sheets of A4 paper (one for each day), and patients were given a pre-paid envelope to return the completed questionnaire. 10 subsequent patients (Group 2) were given the domiciliary facial cooling system (Hilotherm®) to use for up to 7 days and were also asked to complete the same survey. An additional section was added to record patient satisfaction with the unit. After completion this survey was returned anonymously in a sealed envelope. Both groups received advice on post-operative analgesia.

The Hilotherm® domiciliary facial cooling system consists of a mid/ lower face pre-fabricated, polyurethane face-mask that is secured by 2 velcro® straps to go around the head. It is connected to a unit that can be filled with either cooled blocks or ice, and filled with tap water. This cooled water, regulated at around 15°C, circulates around the mask to channel the water to the lower face of the patient. Patients were given the manufacturer's instruction leaflet, but were not showed how to apply or assemble the system before discharge. They were advised to use it daily for as long or as little as they wished.

For each questionnaire returned, the responses were collated in an anonymised database for each group. The response to questions 1-5 was coded following published guidance (euroqol.org) as follows; no complaint - score of 1, some problems - score of 2, a lot of problems - score of 3. For questions 1-5, The mean responses to questions 1-5 were calculated as the sum of all responses across the week, where higher scores indicate greater impact on QoL in that domain. The response to question 6, a visual analogue scale (VAS), was recorded as a numerical value lying closest to where the line drawn by the patient crossed the scale. The results for all respondents were collated and a mean score of responses to question 6 with confidence intervals was calculated for each day. The lower scores indicate a greater impact on overall QoL. An ANOVA test was performed to assess for change in mean VAS score over time, with a post-hoc test between groups. Pairwise correlation of total scores for questions 1-6 was performed. All statistical analysis was undertaken using statistical package STATA (Statacorp 2015. Stats Statistical Software: Release 14 College Station, TX:StataCorp LP).

On discussion with our local institutional research and development review board they granted an exception from the requirement for ethical approval for both groups in this prospective service evaluation. This is because we routinely use a non-domiciliary facial cooling unit for patients following orthognathic surgery. We also routinely advise patients on the use of cold compresses following M3M removal.

RESULTS

Results 1: Group 1 - Generic QoL following M3M removal

Of the 20 patients in Group 1 invited to take part, 14 returned surveys anonymously (response rate of 70%). The completion rate of the EQ5D3L was 100% by respondents.

Results 2: Group 2 - Generic QoL following M3M removal with domiciliary facial cooling

All 10 patients invited to evaluate the Hilotherm® domiciliary facial cooling system accepted its use. Questionnaire response rate was 100%, and completion was 100%. This was made up of 3 males and 7 females. The mean age of respondents was 21 years and 6 months.

Results 3: Collated responses of questions 1 – 5 of EQ5D3L Part 1 (Figure 1) Groups 1 & 2.

In all 5 items, QoL was reduced and then improved during the early post-operative period. By day seven, no individuals reported severe reduction in QoL for any item. The greatest reduction in QoL on every day, was in the pain or discomfort item. Each day QoL was improved for Group 2 compared to Group 1 demonstrated in a radar graph (Figure 4).

Results 4: Part 2 EQ5D3L (Figure 2) was calculated for a 20cm vertical VAS. This is a score of global well-being which was recorded each day post-operatively, and scored out of 100. Respondents' results from Groups 1 & 2, were collated separately, and a mean score for each day calculated. The mean and the trend, is shown in the graph in Figure 3 for both groupsVAS scores improved at approximately 5.7 points per day during the first week after M3M removal.. Considered across all 7 days, the mean VAS scores were approximately 7.8 points better in participants who received domiciliary cooling compared to participants who did not ($p = 0.004$).

Results 5: Daily use (in hours) patients in Group 2 applied the Hilotherm® domiciliary facial cooling system. The daily mean for use is displayed in Table 1. None of Group 2 used the domiciliary unit on day 7, and used it very little on day 6.

Results 6: Ease of use and comfort of domiciliary facial cooling system.
Experience of the domiciliary facial cooling system was positive (Figure 5). All patients that used the unit gave either positive or very positive feedback. On the whole the group found it unit easy to use, comfortable and said that the temperature was ideal. The mean "usefulness" was 7.8 out of 10 (10 = maximum usefulness).

DISCUSSION

Complications following M3M surgery have been published (2,4,5,6,7), but less evidence is available describing patient's generic QoL in the early post-operative period. Recently, the importance of patient reported outcome measures (PROMS), are being recognised during the commissioning of healthcare services in the UK (11,12,13), as is the importance of providing information regarding risks and side effects of procedures during the consenting process. For these reasons, interventions which mitigate the side effects of surgery are of interest to providers and patients.

Traditionally cold compresses have been used to treat pain and swelling in the period directly following bodily injury or surgery (14). Studies in oral and maxillofacial surgery have compared the application of traditional cold compresses vs the Hilotherm® non-domiciliary facial cooling system on swelling following orthognathic surgery (15,16), bilateral mandibular fracture fixation (17), zygomatic fracture fixation (18), face lift surgery (19) and third molar extraction (20,21).

Cold therapy has effects on nerve conduction, local vasculature, muscles and metabolic process (22). Physiological cooling is known to exert an autonomic-mediated effect which induces vasoconstriction which, in theory, should minimize oedema and ecchymosis of the tissues (23). Cold compresses often have a temperature which starts at around 0°C and rapidly warms to room temperature, compared to a Hilotherm facial cooling system that constantly runs at around 15°C. This is the temperature at which vasoconstriction is at its most intense and hence should have the best anti-oedema effect. Peripheral nerve conduction, inflammation and pain, is also reduced (22).

Below 15°C these effects are reduced, and at 0°C, nerve conduction is completely disabled and vasoconstriction reverts to vasodilation. Extreme low temperatures also constrain lymph drainage and cell metabolism, which increases oedema (22). Keeping constant cooling temperature over the operation site at around 15°C should result in a reduction in pain and swelling, and consequently improve QoL in the early post-operative period. Two recent systematic reviews and meta-analyses (9,24) have described a significant improvement in pain and swelling after facial surgery with the use of a hilotherapy system. Jones et al measured pain on a VAS (19) similar to the EQ5D3L Part 2 (Figure 2), but none of these studies have examined the impact on QoL.

In our service evaluation we demonstrate a significantly improved QoL for the 7 days of the evaluation, when comparing Group 1 (no cooling unit) and Group 2 (domiciliary facial cooling unit). Of particular note is the improvement seen on the EQ5D3L Part 2 VAS scoring for Group 2 vs. Group 1 on days 3-5. These results are in keeping with current literature findings

that facial cooling therapy improves patient perception of pain and swelling most notably on Day 2 post-surgery (9,19, 24).

"Return to normal activities" was sooner in Group 2 of our evaluation suggesting that the domiciliary facial cooling system improves the post-operative experience for both physical symptoms i.e. "pain/ discomfort" and also general personal well-being i.e. "overall QoL". "Anxiety/ worry" was also improved every day post-surgery in Group 2 vs Group 1. These findings support the idea that addressing "pain/ discomfort" improves the domains of "anxiety/ worry", and "overall QoL" has been demonstrated in this group of patients.

Experience of the ease of use and comfort of the domiciliary facial cooling system was positive. The duration of use of the system (Table 1) was also interesting. Our results demonstrate the biggest difference in QoL between Groups 1 & 2 on days 3-5 and since the use of the unit diminishes at that point, this would tend to support the suggestion that the unit was only necessary in the 5 days post-operatively. This means there are 2 days in which this could be used by another patient. This type of information has value when compiling a business case to gain funding for a new form of treatment or intervention.

Our evaluation has several limitations and the therapeutic effects should be interpreted with caution. 6 patients (30%) patients in Group 1 did not complete the EQ5D3L and return it to us. If these patients had a better post-operative experience than the people who returned their surveys this could have resulted in a reporting bias which over-estimates how bad the early post-operative experience was, and give the appearance that the facial cooling unit improved QoL more than it did.

Our sample size is small, as there were no prior power calculations, therefore we acknowledge the lack of precision our results may give. As our study was a feasibility or pilot study we felt a prior power calculation was not necessarily appropriate (25) and we also had no prior indication as to the likely difference in PROMs between both groups. The difference in PROMs between the two groups could be used as a basis to power a future randomised control trial leading on from this study with larger numbers of participants.

Another limitation is that the evaluation was not blinded. Group 2 knew they were using the facial cooling unit and there may have been a placebo effect to give more favourable answers because they felt they were receiving a new treatment. After M3M removal they were reassured that their questionnaires were to be placed in a sealed and unmarked envelope giving anonymity, and the forms were completed in the privacy of participants own homes which mitigated against bias.

There was no objective measurement of pain and swelling in the patients included in this project, but since this study focusses on QoL we do not consider this a significant weakness. QoL was also not recorded on an EQ5D3L questionnaire directly pre-operatively in either group, and is recognised as a minor limitation of this study. As the therapeutic effects of hilotherapy have already been proven (9,24) this evaluation was not designed to prove efficacy, but simply to evaluate the ease of use, and the effect of using hilotherapy in a domiciliary setting, on generic QoL following M3M removal.

CONCLUSION

EQ5D3L has been shown to be a responsive tool in the assessment of QoL following M3M removal. It evaluates generic QoL providing data on return to normal activities, and patient perception of improvement in pain and swelling, which is information our patients have reported is most important to them.

With the growing importance of patient reported outcome measures (PROMs) following medical intervention, it is necessary to look at ways to improve these outcomes. This evaluation suggests that a domiciliary facial cooling system is easy to use, and improves QoL in the early postoperative period following M3M removal.

Conflict of Interest: there is no conflict of interest. Specifically we have not been given any incentive for this project by Hilotherm GmbH.

Ethics statement/confirmation of patient permission

No patient permission was requested as no clinical details or identifying information was recorded or disclosed. No ethical approval was required as the project was a service evaluation not clinical research.

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Figure/ table legend

Table 1: Length of time in hours that patients in Group 2 applied the Hilotherm® domiciliary unit each day.

Figure 1: EQ5D5L Survey Part 1

Figure 2: EQ5D5L Part 2 visual analogue scale (VAS)

Figure 3: Change in mean VAS over time EQ5D5L Part 2 Groups 1 & 2

Figure 4: Collated and compared responses of questions 1 – 5 of EQ5D5L Part 1 (Figure 1) Groups 1 & 2

Figure 5: Patient satisfaction of hilotherapy unit